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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/994,444	11/27/2001	Elizabeth Esther Mary Bates	DX0669KB	1324

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SCHERING-PLOUGH CORPORATION
PATENT DEPARTMENT (K-6-1, 1990)
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EXAMINER

EWOLDT, GERALD R

ART UNIT	PAPER NUMBER
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1644

DATE MAILED: 06/17/2003

13

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/994,444

Applicant(s)

Bates et al.

Examiner

G.R. Ewoldt, Ph.D.

Art Unit

1644



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Apr 8, 2003
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above, claim(s) 1-10 and 19 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 11-18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 6 6) ☐ Other: _____

DETAILED ACTION

1. Applicant's election without traverse of Group VIII (a polynucleotide encoding the polypeptide referred to as A07C03), Claims 11-18, and the species SEQ ID NO:8, in Paper No. 12, is acknowledged.

Note that the claims are only under examination as they recite the polynucleotide encoding the polypeptide referred to as A07C03.

2. Claims 1-10 and 19 are withdrawn from further consideration by the examiner, 37 C.F.R. § 1.142(b) as being drawn to nonelected inventions.

3. The specification is objected to as follows: the first line of the specification must be updated to include the issuance of application number 08/978,289 as U.S. Patent No. 6,361,939.

4. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

5. Claims 11-18 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well-established utility.

Applicant is directed to the Utility Examination Guidelines, Federal Register, Vol. 66, No. 4, pages 1092-1099, Friday January 5, 2001. In keeping with the revised utility guidelines (available on the USPTO Website), none of the disclosed uses is a specific, credible, and/or substantial use.

The instant claims are drawn to a polynucleotide encoding the polypeptide referred to as A07C03, as well as additional polynucleotides comprising various degrees of homology to the original polynucleotide, as well as cells expressing the polynucleotide. The specification asserts at page 18 that the claimed polynucleotides are useful "to isolate genes from other species". The protein encoded by the claimed polynucleotide is asserted to be useful "for generating antibodies." The antibodies could then be useful for screening expression libraries. Clearly, what the specification discloses is that the claimed invention is useful essentially for studying itself. Said study is not considered to be a specific and substantial

asserted utility or a well-established utility. At page 59, the specification discloses that the claimed "DNA or RNA may be used as a component in a forensic assay," however, no specific assays are disclosed. Again, this use is not considered to be a specific and substantial asserted utility or a well-established utility. Therapeutically, the specification discloses that the protein encoded by the claimed polynucleotide "may be useful in the treatment of conditions associated with abnormal physiology or development, including abnormal proliferation, e.g., cancerous conditions, or degenerative conditions." However, no correlation or connection between the polynucleotides of the instant claims, nor the proteins they might encode, with any "abnormal physiology" or conditions is established. Again, this use is not considered to be a specific and substantial asserted utility or a well-established utility.

As set forth in the oft-quoted *Brenner v. Manson*, 383 U.S. 519, 532 (1966), "But a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion." Clearly, in this case, Applicant has failed to disclose an adequate conclusion, i.e., Applicant has failed to disclose a specific and substantial asserted utility or a well-established utility for the claimed invention.

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 11-18 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by a credible utility, for the reasons set forth above, one skilled in the art would not know how to use the claimed invention so that it would operate as intended without undue experimentation.

8. Claims 11-18 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention.

Under *Vas-Cath, Inc. v. Mahurkar*, 19 USPQ2d 1111, 1117

(Fed. Cir. 1991), to satisfy the written description requirement, an applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention, and that the invention, in that context, is whatever is now claimed.

There is insufficient written description to show that Applicant was in possession of a nucleic acid which:

- A) encodes an antigenic peptide sequence of Table 2;
- B) encodes a plurality of antigenic peptide sequences of Table 2;
- C) exhibits at least about 80% identity to a natural cDNA encoding said segment;
- D) is a hybridization probe for a gene encoding said A07C03;
- E) is a PCR primer, PCR product, or mutagenesis primer;
- F) hybridizes under wash conditions of 30° C and less than 2M salt to SEQ ID NO: 5, 7, or 9;
- G) exhibits at least about 85% identity over a stretch of at least about 30 nucleotides to a primate or rodent A07C03;
- H) said wash conditions are at 45° C and/or 500 mM salt; or said identity is at least 90% and/or said stretch is at least 55 nucleotides;
- I) said wash conditions are at 55° C and/or 150 mM ;alt; or said identity is at least 95% and/or said stretch is at least 75 nucleotides.

The jumbo specification fails to disclose any of the aforementioned species. With the exception of SEQ ID NOS:5 and 7 (which differ by just a few nucleotides), the skilled artisan could not envision the detailed invention of the instant claims. Adequate written description requires more than a mere statement that a component is part of the invention and a reference to a potential method of isolating it. The nucleic acid itself is required. Furthermore, in *The Regents of the University of California v. Eli Lilly* (43 USPQ2d 1398-1412) 119 F.3d 1559, the court held that a generic statement which defines a genus of nucleic acids by only their functional activity does not provide an adequate written description of the genus. The court indicated that while Applicants are not required to disclose every species encompassed by a genus, the description of a genus is achieved by the recitation of a representative number of DNA molecules, usually defined by a nucleotide sequence, falling within the scope of the claimed genus. At section B(1), the court states that "An adequate written description of a DNA ... requires a precise definition, such as by structure, formula, chemical name, or physical properties', not a mere wish or plan

for obtaining the claimed chemical invention". In the instant case, Applicant has not even disclosed a specific function for the claimed polynucleotide, let alone any of the permutations set forth above. Accordingly, one of skill in the art must conclude that the specification fails to disclose an adequate written description or a representative number of species to describe the claimed genus.

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claims 11-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, the recitation of "said A05C03" is vague and indefinite as the clone has no antecedent basis in Claim 1. Further no such clone is disclosed in the specification.

11. No claim is allowed.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Gerald Ewoldt whose telephone number is (703) 308-9805. The examiner can normally be reached Monday through Thursday from 7:30 am to 5:30 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 at 703-872-9306 (before final) and 703-872-9307 (after final).



G.R. Ewoldt, Ph.D.
Primary Examiner
Technology Center 1600
June 16, 2003